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Related per December 5, 2007 Order to Case No.

ABBOTT LABORATORIES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT ON GSK'S AMENDED

## HIGHLY CONFIDENTIAL PURSUANT TO

Honorable Claudia Wilken

Courtroom 2 (4<sup>th</sup> Floor)

Winston & Strawn LLP 101 California Street San Francisco, CA 94111-5802	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE,  Plaintiff,  vs.  ABBOTT LABORATORIES,  Defendant.  RITE AID CORPORATION; RITE AID HDQTRS CORP.; JCG (PJC) USA, LLC; MAXI DRUG, INC D/B/A BROOKS PHARMACY; ECKERD CORPORATION; CVS PHARMACY, INC.; AND CAREMARK LLC,  Plaintiffs,  vs.  ABBOTT LABORATORIES,  Defendant.  MEIJER, INC. & MEIJER DISTRIBUTION, INC.; ROCHESTER DRUG CO-OPERATIVE, INC.; AND LOUISIANA WHOLESALE DRUG COMPANY, INC., ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,  Plaintiffs,	CASE NO. CV 07-5702 (CW) Related per November 19, 2007 Order to Case No. CV 04-1511(CW)  CASE NO. CV 07-6120 (CW) Related per December 5, 2007 Order to Case No. CV 04-1511 (CW)  CASE NO. CV 07-5985 (CW) (Consolidated Cases) Related per November 30, 2007 Order to Case No. CV 04-1511 (CW)
	18 19 20	INC.; ROCHESTER DRUG CO- OPERATIVE, INC.; AND LOUISIANA WHOLESALE DRUG COMPANY, INC., ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,	(Consolidated Cases) Related per November 30, 2007 Order to
	<ul><li>23</li><li>24</li><li>25</li></ul>	ABBOTT LABORATORIES,  Defendant.	
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#### NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

Abbott Laboratories moves, under Fed. R. Civ. P. 56, for summary judgment or alternatively summary adjudication of the antitrust and state-law claims asserted by GlaxoSmithKline ("GSK") in Case No. 07-5702. Abbott is separately moving on the claims asserted by the direct purchaser plaintiffs in Case Nos. 07-5470, 07-6120 and 07-5985. To the extent that claims overlap, the two motions incorporate each other by reference. This Motion is based upon this Notice, the attached Memorandum, the Declarations of Christopher J. Calamari, Joel Hay, Ph.D., and James Hurst (including exhibits), and such material as is presented in Abbott's reply papers or at any hearing.

### MEMORANDUM OF POINTS AND AUTHORITIES

#### INTRODUCTION

This case involves Abbott's decision to increase Norvir<sup>®</sup>'s price in December 2003 – a decision allegedly designed to help Abbott's other HIV drug, Kaletra<sup>®</sup>. GSK asserts claims for federal and state antitrust violations (Counts 1 and 4), breach of contract (Count 2) and violations of North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA") (Count 3). All claims fail.

#### A. The Antitrust Theory Fails

GSK has no evidence on two essential antitrust elements: monopoly power and anticompetitive conduct. For monopoly power, GSK needs proof of Abbott's ability to *maintain* a high market share, where Abbott can restrict marketwide output (thereby driving up prices) because competitors cannot sufficiently increase their own output.

No such evidence exists. Far from having "monopoly" power over the so-called "boosted market" – protease inhibitors ("PIs") boosted by Norvir – Kaletra's leading competitors have increased their output by *more than 600%* since Norvir's price increase. And they did so despite substantially raising their own prices. Also, Kaletra's market share began plummeting *before* the December 2003 price increase, and it is now close to being *the number three product in the market*, behind two other competitors. Even under GSK's ridiculously narrow market definition, Abbott's market share rapidly dropped from 100% in June 2003 to 81% in only six months, and now stands at only 30%. That is the opposite of monopoly power – it is proof of a highly competitive market.

GSK's sole theory of anticompetitive conduct – a purported "refusal to deal" – is equally

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flawed. This Court previously held that GSK must prove that Abbott "essentially refused to deal with competitors" by charging an "exorbitant" price for Norvir such that boosted PIs "could not compete with Kaletra." (1/12/10 Order, Dkt. 195, at 12, 15). To attempt to meet that standard, GSK argues that Abbott effectively made Norvir unavailable for use with rival PIs because Norvir's new price amounted to "an offer that [HIV doctors and patients] could not accept." (Id. at 12). That notion is absurd. Norvir is one of the top-selling HIV drugs. Its sales have more than quintupled since the price increase. In no sane world can that constitute an "effective" refusal to deal.

#### **The Breach Of Implied Covenant Claim Fails**

For its breach of contract claim, GSK asserts that Abbott (a) implicitly agreed to fix the price of its HIV drug Norvir, subject to "inflation-level price increases"; and then (b) breached that contract by raising Norvir's price to \$8.57 for the most common daily dose in a market crowded with drugs priced at \$20 to \$30 per day. But the parties' actual agreement was a simple patent license allowing GSK to co-market its PIs with Norvir without infringing Abbott's patents. The contract does not address Norvir's price at all. Yet, GSK alleges that, in this routine and non-exclusive license agreement, Abbott *implicitly* waived its right to set Norvir's price as it deemed appropriate.

Under controlling New York law, courts should be "extremely reluctant" to "impliedly" add terms "the parties have neglected to specifically include." Vermont Teddy Bear Co. v. 538 Madison Realty Co., 1 N.Y.3d 470, 475 (N.Y. 2004). This case is no exception. In fact, the Court should grant Abbott summary judgment on GSK's contract claim for at least the following reasons.

First, as a matter of undisputed fact, the parties intentionally avoided entering into any agreement about Norvir's pricing levels.

There is nothing to support the utterly illogical notion that the parties *implicitly* reached an agreement they *intentionally avoided* reaching.

Second, a party always has the "right to act on its own interests in a way that may incidentally lessen the other party's anticipated fruits from the contract." M/A-COM Sec. Corp. v. Galesi, 904 F.2d 134, 137 (2d Cir. 1990) (applying New York law). An implied promise giving up that right can "be recognized only if it is clear that a reasonable [party] would not have entered into

the [contract] without such an understanding," which is the only situation in which refusing to "recognize such a covenant would . . . deprive the [plaintiff] of the fruits of his bargain." *Rowe v*. *Great Atl. & Pac. Tea Co.*, 46 N.Y.2d 62, 69-70 (N.Y. 1978).

GSK cannot meet this standard. Far from showing that no reasonable party would have obtained a Norvir patent license absent an implicit price-fixing agreement, multiple other sophisticated pharmaceutical companies *have* taken licenses without agreeing on Norvir's price. Pfizer even took a license six months *after* Norvir's price increase. And GSK not only took the same deal, but – contrary to the notion that Norvir's price increase "devastated the value of the license agreement to GSK" by purportedly "restricting patient access" (Am. Compl. ¶ 69) – GSK has taken full advantage of its worldwide license for over *six straight years*. Since 2003, GSK has continuously promoted its own HIV drugs with Norvir globally, resulting in sales totaling more than *a billion dollars*. GSK has no evidence showing any reasonable party would have placed those sales at risk of an injunction and/or infringement damages without an implicit price-fixing agreement.

Third, GSK's implied covenant claim also fails for the independent reason that there is no available remedy. Controlling precedent and the license agreement itself preclude GSK from recovering consequential damages such as lost profits. This limits GSK's remedy to payments it made under the parties' contract in return for the allegedly breached promise to restrain Norvir's domestic price.

GSK thus has no compensable remedy.

#### C. The UDTPA Claim Fails

GSK's alternative claim under the UDTPA is equally flawed. Under settled North Carolina law, a party that cannot properly maintain a contract and/or antitrust claim cannot salvage its failed case simply by asserting a UDTPA claim. Moreover, under North Carolina law, what constitutes "unfair" and "deceptive" conduct is an issue of law, and GSK has offered no evidence here supporting any legally cognizable "unfair" and "deceptive" conduct. The UDTPA claim, like the flawed antitrust and implied covenant claims, should be rejected as a matter of law.

#### **BACKGROUND**

The Court is familiar with this case, which concerns Abbott's December 2003 decision to re-

As of 2001, HIV patients were taking GSK's PI Agenerase, which was a predecessor drug to GSK's drug Lexiva, boosted by Norvir. Because Norvir was covered by multiple patents in multiple (Ex. A, Weinstock Dep. at 49:3-50:22 & Ex. 12). (See id.; Ex. B, Key Dep. at 91:21-25). There is no dispute about the extraordinary level of sophistication the parties brought to the negotiation. John Keller, GSK's Vice President for Worldwide Business Development, was "the lead person responsible for negotiating contracts for HIV drugs." (Ex. C, Keller Dep. at 41:8-10). (See id. at 41:8-10, 272:2-21). (See id. at 272:22-274:6). This is undisputed. (Id. at 275:25-

(Ex. B, Key Dep. at 188:17-19; see also Ex. D, Hannan Dep. at 95:23-

97:22 (same); Ex. E, Poulos Dep. at 72:3-17).

Unless otherwise noted, exhibit numbers refer to the Declaration of James F. Hurst.

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CASE Nos. 07-5470, 07-5985, 07-6120, 07-5702 (CW) ABBOTT LABORATORIES' MOTION FOR SUMMARY JUDGMENT ON GSK'S AMENDED COMPLAINT 101 California Street San Francisco, CA 94111-5802

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(Ex. B, Key Dep. at 117-118 (emphasis added)).
(Calamari Decl. Ex. 2
¶ 3.4(a); see also Ex. B, Key Dep. at 106:16-118:23 & Ex. 129 ("
")).
D. The Norvir Price Increase Did Not Prevent GSK From Profiting On Its Co-
Promotion Of Lexiva With Norvir.
In November 2003, GSK launched Leviva, which can be co-prescribed with Norvir under the

November 2003, GSK launched Lexiva, which can be co-prescribed with Norvir under the License. (Ex. G, Morgan Dep. at 180:15-20.) Lexiva competes with Abbott's Kaletra, a coformulation of ritonavir and Abbott's PI lopinavir. (See Am. Compl. ¶¶ 19, 45).

(see Ex. D, Hannan Dep. at 78:9-13, 82:18-

83:14), which have generated more than a billion dollars for GSK. (See Hay Decl. ¶¶ 8-9).

GSK now claims that Abbott "destroyed" the value of the agreement in December 2003.

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(See Ex. H, Prowse Dep. at 242:11-243:16, 254:2-

255:12). Since then, it has never stopped promoting the combined use of Norvir with Lexiva. (See id. at 241-45, 251). For six straight years, GSK has promoted Norvir's power to boost Lexiva – promotions that have continued during this lawsuit. Even today, GSK's Lexiva website touts the benefits of taking Lexiva with Norvir, which included boosted efficacy and fewer pills:

## HIV medicine with fewer pills

LEXIVA is often taken with another HIV medicine called Norvir® (ritonavir). Norvir boosts the effect of LEXIVA by making it last longer in the body. LEXIVA can be taken with half of the usual boosting dose of Norvir-100 mg (1 pill) versus 200 mg (2 pills). Half the amount of Norvir means that you may have fewer pills to take and keep track of every day, as well as more convenience.

(Ex. I, Lexiva web site, found at http://www.lexiva.com/about-lexiva/lexiva-with-ritonavir.html).

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At no point since December 2003 has Abbott removed Norvir from the U.S. market, or otherwise restricted its supply. (See Ex. B, Key Dep. at 184:20-185:9). On the contrary, since the December 2003 price increase, prescriptions of Norvir – used almost entirely to boost PIs – have more than *quintupled*. (Hay Decl. ¶ 6).

With this rise in Norvir prescriptions, GSK's Lexiva sales have substantially increased. As GSK admits, "in each calendar year that Lexiva has been on the market from 2004 to 2008, GSK has sold a greater number of Lexiva tablets than in the calendar year preceding each such calendar year." (Ex. J, GSK Answer to RFA 196). As GSK and others promoted the use of Norvir to boost their own drugs, the prescription volume for Norvir skyrocketed. Norvir is one of the most prescribed HIV drugs. (See Ex. B, Key Dep. at 184:20-185:9; Hay Decl. ¶ 6).

#### **ARGUMENT**

Abbott is entitled to summary judgment on GSK's claims for federal and state antitrust violations, breach of the implied covenant of good faith and fair dealing, and violation of the North Carolina UDTPA. Summary judgment is proper here, where no genuine issues of material fact remain in dispute and GSK's claims fail as a matter of law. Jespersen v. Harrah's Operating, 444 F.3d 1104, 1106 (9th Cir. 2006); see also Fed. R. Civ. P. 56. "A mere scintilla of evidence" is "insufficient; there must be evidence on which a jury could reasonably find for the non-moving party." *Rivera v. Philip Morris*, 395 F.3d 1142, 1146 (9th Cir. 2005).

#### I. GSK's Antitrust Claims Fail Based On Undisputed Facts.

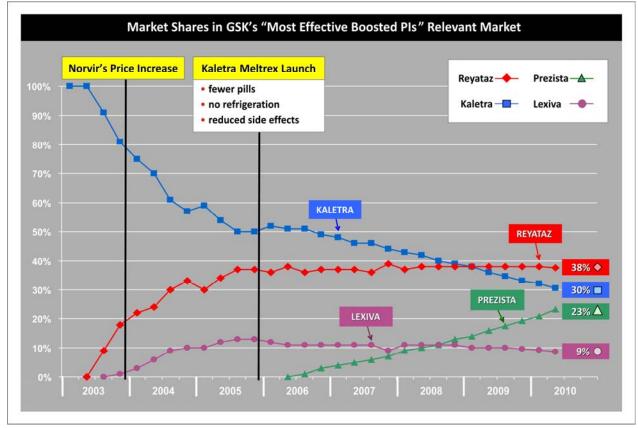
GSK's antitrust claims fail because it cannot satisfy either the monopoly power or anticompetitive conduct elements.

#### Abbott's Rapidly Falling Market Share Refutes Any Claimed Monopoly Power. Α.

Proving that Abbott has monopoly power requires evidence that it can "control prices or exclude competition." Oahu Gas Service, Inc. v. Pacific Resources Inc., 838 F.2d 360, 366 (9th Cir. 1988). This generally requires at least a "sixty-five percent market share." (5/16/08 Order, Dkt. 516, in *Doe* at 10 (citation omitted). And even with a high market share – even well above 65% – the Ninth Circuit has emphasized that, "[i]n evaluating monopoly power, it is not market share that counts, but the ability to maintain market share." United States v. Syufy Enters., 903 F.2d 659, 665-

66 (9th Cir. 1990) (emphasis added). For instance, in a case where the defendant's market share dropped from 93% to 75% in about three years, the Ninth Circuit emphasized that the district court "would do better to plot the [market share] points on a graph and observe the pattern they form than to focus narrowly on [defendant's] market share at a particular time." *Id* at 666.

Plotting market share points on a graph shows no monopoly power here. Even under GSK's ridiculously narrow market definition — which excludes products other plaintiffs consider competitors — Abbott's share dropped like a rock after Reyataz launched in mid-2003 from 100% to 81% in just six months, all before the Norvir price increase. (Ex. K, Noll Rep. Ex. 4a). Since then, as indicated below, Abbott's share has dropped all the way to 30%:



(Hay Decl. ¶ 4 & Ex. 3).

GSK's antitrust claims also fail because, as this chart shows, no rival was excluded from the market. Instead, rivals have dramatically increased their output and, in fact, have effectively taken over the market. The Ninth Circuit has held that summary judgment is warranted where, as here, the defendant lacked power to "restrict marketwide output and, hence, increase marketwide prices." *Rebel Oil Co., Inc. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995). A monopoly

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requires reduced marketwide output, reflecting the monopolist's ability to restrict output to drive up prices. Id. In contrast, output from Abbott's rivals collectively has increased more than 600% since the price increase. (See Hay Decl. ¶ 5). It is thus absurd to say Abbott has a monopoly.

#### В. Norvir's Rapidly Rising Sales Refute Any Alleged Refusal To Deal.

GSK's antitrust claims fail for an independent reason – the undisputed evidence cannot satisfy the necessary element of anticompetitive conduct. Unlike the direct purchaser plaintiffs, GSK does not allege predatory pricing. Its sole theory of anticompetitive conduct is an alleged refusal to deal. While "businesses do not have a duty to aid competitors," this Court has held that a refusal to deal with a competitor can be actionable "when a defendant voluntarily alters a course of dealing and 'anticompetitive malice' motivates the defendant's conduct." (Id. at 13 (citing Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985), and Verizon).

Based on the legal standard this Court set when declining to dismiss at the pleading stage, GSK can survive summary judgment only by proving that Abbott (a) "essentially refused to deal with competitors" by pricing Norvir such that boosted PIs "could not compete with Kaletra"; and (b) terminated a prior voluntary course of dealing under which Abbott "induced Abbott's competitors to rely on Norvir's availability on the market, subject to normal, inflation-level price increases." (1/12/10 Order at 14-15). Plaintiffs cannot satisfy either element.

#### 1. Plaintiffs Have No Evidence Of An Effective Refusal To Deal.

This Court relied heavily on Aspen Skiing in finding that GSK adequately alleged that "Abbott essentially refused to deal with its competitors." (Id. at 15). In that case, rival ski resorts agreed to offer jointly a ski lift pass that could be used at any of the parties' resorts. Believing the joint marketing arrangement was becoming unprofitable, the defendant refused to continue dealing with plaintiff, even on plainly profitable terms. Instead, it "extended the plaintiff 'an offer that it could not accept[.]" (Id. at 12 (quoting Aspen Skiing, 472 U.S. at 592)).

The undisputed facts here do not fit within the Aspen Skiing framework. According to GSK, Abbott has essentially refused to continue its "deal" to allow GSK and other rivals to co-market their boosted PIs with Norvir. Plaintiffs do not – because they cannot – allege an actual refusal to deal. This is because Abbott "never refused outright to sell Norvir." (Id. at 15). The Court nonetheless

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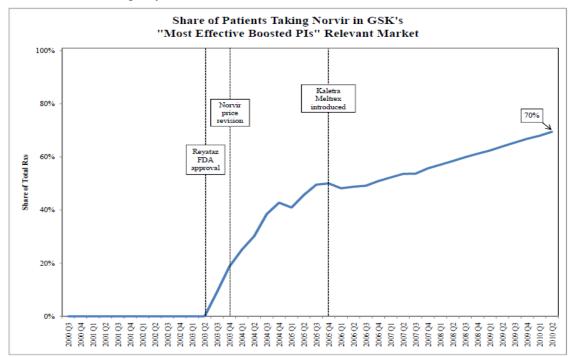
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held that conduct tantamount to a refusal to deal is actionable even in the absence of an outright refusal. As the Court put it, a refusal to deal may exist "when a monopolist sets exorbitant terms that a competitor would not accept." (Id. at 15 (citing MetroNet Svcs. Corp. v. Qwest Corp., 383 F.3d 1124, 1132 (9th Cir. 2004)). Under the Court's standard, however, GSK still must show that rivals "could not compete with Kaletra." (1/12/10 Order at 15). GSK's theory thus turns on whether Abbott set exorbitant terms for selling Norvir such that it became "an offer" that consumers "could not accept," thereby effectively refusing to deal. Aspen Skiing, 472 U.S. at 592. Plaintiffs cannot come even close to making this showing.

First, far from being an offer consumers "could not accept," Norvir prescriptions have quintupled since the repricing. Indeed, it is now one of the most prescribed HIV drugs – a far cry from being withdrawn from the market. (Hay Decl. ¶ 6). Norvir's prescription volume has grown rapidly as a companion to boostable PIs in GSK's most narrowly defined relevant market – which includes only Kaletra as well as boosted Reyataz, Lexiva and Prezista. As the chart below shows, the share of patients taking Norvir with a PI in this market has grown from 0% (before the Reyataz launch when Kaletra allegedly owned 100% of the market) to its current share of 70%:



(See Hay Decl. ¶ 7 & Ex. 4). In other words, 70% of patients taking a drug in GSK's relevant market are also taking Norvir. The dramatic increase in Norvir prescriptions utterly refutes the

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notion that Abbott's new price for Norvir amounted to an offer consumers "could not accept."

Second, PIs boosted by Norvir, including GSK's Lexiva, have thrived in the market – something that would be impossible had Abbott actually refused to make Norvir available. Reyataz is now the top-selling boosted PI, taking 20% of the market (under GSK's market definition) in just six months after its launch, with a current share of 38%. (Ex. K, Noll Ex. 4a). And, again, Lexiva has made more than \$1 billion in sales when boosted since its launch. (Hay Decl. ¶¶ 8-9). This fact also utterly refutes the notion that Abbott has "refused to deal" with respect to Norvir.

Third, contrary to the notion that Norvir's new price rendered the drug unavailable, there is no evidence that any doctor changed prescribing habits on the ground that Norvir cost too much:

- GSK's expert: "Q. Did you personally decide to take somebody off of Norvir as a result of the price increase when the patient themselves did not insist on it? A. Never, sir. (Ex. L, Siddiqui Dep. at 257:6-9; see also id. at 271:11-18 (testifying he was not "aware of any physicians who . . . switched a patient from a Norvir-based regimen to Kaletra as a result of a Norvir price increase")).
- Direct Purchasers' expert: "O. Did [the Norvir price increase] impact your prescribing decisions in any way? A. Not mine. . . . Q. Because your patients don't pay for their drugs? A. Correct." (Ex. M, Richman Dep. at 128:3-8; see also id. 131:14-17 ("So as you sit here today, you can't identify a single doctor who changed their prescribing habits as a result of the Norvir price increase -- A. Right.").
- Abbott's expert: "I did not take a single patient off of Norvir because of the December 2003 price increase. . . . I am also not aware of any other physicians who, because of the Norvir price increase, took patients off of Norvir[.]" (Ex. N, Marzouk Rep. at ¶¶ 121, 123).

Fourth, Norvir's new price was hardly an offer consumers "could not accept" because only a tiny percentage of patents paid any portion of the price increase. GSK's own marketing expert, Dr. Dolan, readily admitted that, in the "typical case," the price paid by an HIV patient "didn't change" after the Norvir repricing because of insurance and government programs. (Ex. O, Dolan Dep. at 140:19-141:2). In any event, even after the price increase, Norvir remains one of the *lowest* priced

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HIV drugs and costs less than half the average HIV medication price. (Hay Decl. ¶ 10).

In sum, the undisputed facts preclude a finding that Abbott "effectively" refused to deal with respect to Norvir such that competitors "could not compete with Kaletra." (1/12/10 Order at 15 (emphasis added)). Indeed, that notion is ridiculous given that, among other things, Kaletra's competitors have taken over the market while Norvir's sales have more than quintupled. Because Norvir is freely available and used in record quantities, GSK essentially wants this Court to regulate the dynamic pricing relationships among Kaletra and rival boosted PIs. But as the Supreme Court repeatedly emphasized: "No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremedia[ble] by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency." Pac. Bell Tel. v. linkLine Comm'cs., 129 S. Ct. 1109, 1121 (2009) (citations omitted). This is especially true where, as here, "courts would be aiming at a moving target, since it is the interaction between these two prices that may result in" the alleged effective refusal to deal. Id.

#### 2. Plaintiffs Also Cannot Prove That Abbott Terminated A Voluntarily Deal With Rivals To Fix Norvir's Price.

GSK's claim still fails even if one were to assume that the Norvir repricing amounted to an "effective" refusal to deal such that Abbott's rivals "could not compete with Kaletra." This is because GSK cannot establish the second prong of this Court's standard based on Aspen Skiing – i.e., Abbott walked away from a voluntary and profitable course of action. (1/12/10 Order at 12-13).

Almost 20 years after Aspen Skiing, the Supreme Court in Verizon sharply limited this refusal-to-deal theory of anticompetitive conduct, holding that "Aspen Skiing is at or near the outer boundary of § 2 liability." Verizon, 540 U.S. at 409. The Supreme Court rejected this theory in a case where the plaintiff failed to allege the existence and termination of "a voluntary (and thus presumably profitable) course of dealing" – i.e., "a cooperative venture" with a rival. Id. The Supreme Court held that such evidence is necessary to show "a willingness to forsake short-term profits to achieve an anticompetitive end." Id. In light of Verizon, this Court held that GSK must prove Abbott's price increase terminated a voluntary, and thus "presumably profitable," deal between Abbott and its rivals. (1/12/10 Order at 12-13) (quoting Verizon, 540 U.S. at 409).

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Unlike Verizon, MetroNet involved a change in a prior, voluntary course of dealing. 383 F.3d at 1132. But the Ninth Circuit still granted summary judgment because the plaintiff produced no evidence of either (a) a "sacrifice of short-term profits for long-term gain from the exclusion of competition," or (b) a refusal to deal "on the same terms that it deals with direct consumers":

In sum, MetroNet does not fall within the Aspen Skiing exception to the general "no duty to deal" rule, because Qwest's switch to per location pricing does not entail a sacrifice of short-term profits for long-term gain from the exclusion of competition and because Qwest has not refused to deal with MetroNet on the same terms that it deals with direct consumers.

383 F.3d at 1134. The Court of Appeals reached this holding even though the record showed that the defendant's products could not effectively "address[] competition" from plaintiff. *Id.* at 1128. Indeed, the court accepted the assertion that the defendant changed its pricing practices in a way that made it "unprofitable" for rivals to compete, hoping to "win back market share." *Id.* at 1128, 1132.

Given this authority, GSK must first show under Verizon that Abbott voluntarily entered into a presumably profitable "cooperative venture" with rivals to fix Norvir's price. Even if it were to do so, however, GSK also must show under MetroNet that Abbott raised Norvir's price to exclude rivals either by (a) sacrificing short-term profits for long-term gain, or (b) dealing with rivals and consumers on different terms. GSK cannot meet this standard as a matter of law.

As in *Verizon*, Abbott never entered into any kind of a deal with its rivals – including GSK, as explained in detail below – to limit Norvir's price. As discussed in more depth below, the license agreements at issue here do not even mention Norvir's price, let alone a cooperative venture with rivals to constrain that price "to normal, inflation-level price increases" as alleged. (1/12/10 Order at 14). Thus, GSK cannot prove the existence of "a voluntary (and thus presumably profitable) course of dealing" to fix Norvir's price, as required by Verizon. 540 U.S. at 409. By offering licensing agreements, Abbott simply agreed to let rivals co-market their boosted PIs with Norvir without threat of infringement litigation – something they continue to do to this very day.

Even assuming such a counter-factual "deal," GSK still could not satisfy the MetroNet summary judgment standard. First, GSK has failed to show that the net effect of Abbott's conduct

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was to sacrifice short-term profits for long-term gain. To meet this standard, GSK would have to show that Abbott lost more in licensing revenue due to allegedly lower Norvir sales than it gained from the extra profits on each Norvir sale. GSK has made no effort to make that showing. Nor could it. Obviously, raising Norvir's price increased Abbott's profits, especially since Norvir's prescription volume has more than quintupled since the price increase. (See Hay Decl. ¶ 6). Second, it is undisputed that Abbott does not sell Norvir to its rivals and consumers on different terms.

Although the Court allowed GSK's theory to survive the pleadings stage, the Ninth Circuit in MetroNet held that summary judgment is warranted under these circumstances. Indeed, as the Ninth Circuit explained, even conduct that changes a voluntary prior course of dealing for the purpose of "win[ning] back market share" simply cannot raise a triable issue. *MetroNet*, 383 F.3d at 1128.

#### II. Abbott Is Entitled To Summary Judgment On GSK's Claim For Breach Of The Implied Covenant of Good Faith and Fair Dealing.

Under New York law, GSK bears a "heavy burden" of demonstrating the existence and breach of an implied promise. Rowe v. Great Atl. & Pac. Tea Co., 46 N.Y.2d 62, 69 (N.Y. 1978). It is black-letter law that a party cannot invoke the duty of good faith and fair dealing "to create independent contractual rights." Nat'l Union Fire Ins. Co. v. Xerox Corp., 25 A.D.3d 309, 310 (1st Dep't 2006). This is because "the obligation of good faith does not create obligations that go beyond those intended and stated in the language of the contract." Wolff v. Rare Medium, Inc., 210 F. Supp. 2d 490, 497 (S.D.N.Y. 2002) (applying New York law).

Moreover, where, as here, a contract is negotiated by sophisticated, counseled business people, "courts should be extremely reluctant to interpret an agreement as impliedly stating something which the parties have neglected to specifically include." Vermont Teddy Bear Co. v. 538 Madison Realty Co., 1 N.Y.3d 470, 475 (N.Y. 2004) (quoting Rowe, 46 N.Y.2d at 72). This is particularly true because "the implied covenant does not extend so far as to undermine a party's general right to act on its own interests in a way that may incidentally lessen the other party's anticipated fruits from the contract." M/A-COM, 904 F.2d at 137 (quotations omitted).

To carry its heavy burden, GSK must demonstrate not only that it bargained for the alleged

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implied promise, but that a reasonable party actually would not have entered into the License Agreement without it. Courts only "enforce the implied covenant where an implied promise was 'so interwoven in the whole writing' of a contract as to be necessary for effectuation of the purposes of the contract." Id. at 136 (emphasis added). As New York's highest court explained, an implied promise "is to be recognized only if it is clear that a reasonable [party] would not have entered into the [contract] without such an understanding, for it is only in such a situation that it can be said with the requisite certainty that to refuse to recognize such a covenant would be to deprive the [plaintiff] of the fruits of his bargain." Rowe, 46 N.Y.2d at 69-70. Thus, GSK's claim must be rejected "unless the situation is such that the failure to [imply the alleged promises] would be to deprive [GSK] of the benefit of [its] bargain." *Id.*; see also 4/11/08 Order, Dkt. 82, at 21 (finding duties of good faith and fair dealing require that "neither party shall do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract") (quoting 511 West 232nd Owners Corp. v. Jennifer Realty Co., 773 N.E.2d 496 (N.Y. 2002).

GSK purchased freedom to promote Norvir's boosting power without any risk of infringement liability. While GSK has promoted Norvir's ability to boost Lexiva for more than six straight years – Abbott has never asserted any Norvir patents against GSK. GSK has reaped substantial profits, reaching more than a billion dollars in boosted Lexiva sales, which far exceed what it paid for the License Agreement.

Here, GSK received exactly what it bargained for:

GSK alleges that Abbott's price increase breached two "essential" promises that: (1) "Norvir would continue to be commercially available for use as a PI boosting agent," and (2) "future increases in the price of Norvir would be consistent with past increases." (See Am. Compl. ¶ 69; Ex. P; GSK Resp. to Rog. No. 12). As demonstrated below, the undisputed facts show that Abbott neither made nor breached these alleged promises. In any event, summary judgment also is required because GSK does not have a compensable contract remedy.

#### Abbott Did Not Breach An Implied Promise To Make Norvir Available. Α.

GSK first alleges that Abbott breached an *implicit* promised that "Norvir would continue to be commercially available for use as a PI boosting agent." (Am. Compl. 56). This allegation is

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absurd because Norvir has remained commercially available since the parties' agreement.

Norvir is being sold in record amounts, more than almost any HIV drug in history. Norvir's sales have more than *quintupled* since the 2003 price increase. (See Hay Decl. ¶ 6). It is one of the most prescribed HIV drug on the market today, with tens of thousands more patients using Norvir now than in 2003. (Id.). Indeed, the direct purchasers – GSK's co-plaintiffs in this case – are continuing to purchase Norvir in record volumes.

Contrary to GSK's claim that Norvir is not, as a practical matter, "commercially available," GSK has repeatedly admitted that "Norvir is the only drug currently in this market" for PI boosters. (Am. Compl. ¶ 44). GSK's witnesses have likewise admitted that undeniable fact:

- Key was not "aware of . . . any periods of time in which Norvir was not commercially available" since 2003. (Ex. B, Key Dep. at 184:20-185:9).
- Peter Hare, GSK's VP HIV Business Unit, agreed that "Norvir [is] the only effective boosting compound that's currently available." (Ex. Q, Hare Dep. at 39:24-40:1).
- Michael Hannan, who was responsible for commercialization of Lexiva, agreed that "Norvir is still on the market today." (Ex. D, Hannan Dep. at 99:20-22).
- Mark Shaefer, GSK's Director of Clinical Research HIV Division, agreed that, "in HIV therapy, ritonavir is the only commercially available booster that's out there." (Ex. R, Shaefer Dep. at 41:1-7).

To be sure, any argument by GSK that Norvir is commercially unavailable would be frivolous.

#### В. Abbott Did Not Breach An Implied Promise To Limit Norvir's Price.

GSK's second alleged implied promise – that "future increases in the price of Norvir would be consistent with past increases" – goes far beyond what the parties ever intended or agreed. The License Agreement, which contains an integration clause, makes no mention of Norvir's price. GSK thus seeks to insert an entirely new promise into the agreement.

But "the implied covenant of good faith and fair dealing does not provide a court carte blanche to rewrite the parties' agreement." Hartford Fire Ins. Co. v. Federated Dep't. Stores Inc., 723 F. Supp. 976, 991 (S.D.N.Y. 1989). "Nor can a court imply a covenant to supply additional terms to which the parties did not bargain." Id. New York "courts have declined to find that the

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implied covenant of good faith and fair dealing adds to the contract a substantive provision not included by the parties." Geren v. Quantum Chem. Corp., 832 F. Supp. 728, 732 (S.D.N.Y. 1993) (rejecting claim). For at least five reasons, GSK comes nowhere close to meeting the rigorous legal standard for creating an *implied* promise on a subject the sophisticated parties never discussed.

<u>First</u>, there can be no question that GSK is attempting to add a new substantive provision to the License: GSK admits that it did not bargain for any limitation on Norvir's price.

Thus, GSK can hardly argue that Norvir pricing levels were "so interwoven in the whole writing of a contract as to be necessary for effectuation of the purposes of the contract." M/A-COM Sec. Corp., 904 F.2d 134 at 136. Indeed, it defies logic to claim that a topic the parties intentionally avoided became the subject of an implicit agreement. Where, as here, "the contract is intentionally silent as to [a] subject, the implied duty to perform in good faith does not come into play." Dave Gretak Enters. v. Mazda Motors, 622 A.2d 14, 23 (Del. Ch. 1992).

Second, Norvir's price is irrelevant to GSK's contractual right to co-promote its drugs with Norvir under the license. GSK was, and continues to be, free under the license to encourage consumers to take its PIs with Norvir, regardless of its price. GSK not only has received the benefit of this bargain, it has profited handsomely from that benefit. And GSK continues to promote Norvir's boosting power today. GSK cannot seriously argue that any reasonable party would have refused to enter into a license – and given up a billion dollars in sales – absent an implied agreement on Norvir's pricing. As New York's highest court has made clear, implied promises will not be read into an express agreement where, as here, "the contractual objectives were achieved." EBC I, Inc. v. Goldman Sachs, 5 N.Y.3d 11, 23 (2005).

Third, far from establishing that no reasonable party would have entered the agreement without an implied agreement on Norvir's price, some of the most sophisticated pharmaceutical companies in the world did exactly that.

(Calamari Decl. Exs. 22-27).

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that the parties never bargained for. Golub Assocs. Inc. v. Lincolnshire Mgmt., Inc., 1 A.D.3d 237, 238 (1st Dep't 2003). As New York's highest court aptly put it: "Freedom of contract prevails in an arm's length transaction between sophisticated parties . . . , and in the absence of countervailing public policy concerns there is no reason to relieve them of the consequences of their bargain. If they are dissatisfied with the consequences of their agreement, the time to say so [was] at the bargaining table." Oppenheimer & Co., Inc. v. Oppenheim, Appel, Dixon & Co., 86 N.Y.2d 685, 695 (1995) (quotation omitted); see also M/A-COM Sec. Corp., 904 F.2d at 136 (granting summary judgment in favor of defendant on implied covenant claim).

#### C. **GSK Cannot Prove Compensable Contract Damages**

Even if GSK could establish that Abbott breached an implied contract term about Abbott's pricing (which it plainly cannot), GSK's claim would still fail as a matter of law because GSK cannot establish any right to damages. Damages is an element of a breach of contract claim and, thus, a failure to establish a right to damages mandates summary judgment. See Proper v. State Farm Mut. Auto. Ins. Co., 2009 NY Slip Op 5240, 2 (N.Y. App. Div. 2009) ("Failure to prove the essential element of damages is fatal to a cause of action for breach of contract."); Cramer v. Spada, 203 A.D.2d 739, 741 (N.Y. App. Div. 1994) (same).

According to GSK,

(Ex. S, GSK Resp. to Rog. No.

17 (emphasis added)). GSK has no compensable damages under either theory.

First, GSK's request for lost profits is foreclosed by New York law. Parties generally are not entitled to recover lost profits for a breach of the implied duty of good faith and fair dealing. See Travellers Int'l, A.G. v. Trans World Airlines, 41 F.3d 1570, 1576 (2d Cir. 1994). As the Second Circuit put it: "We adhere to the general proposition that a damage award for lost profits cannot rest upon the breach of the implied duty of good faith and fair dealing." *Id.* (applying New York law). While this general proposition does not apply if the lost profits merely "measure compliance with an explicit contract obligation," id., this clearly is not the case here where GSK is seeking lost profits

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This leaves GSK with no compensable contract remedy. Thus, summary judgment also is warranted for failure to prove contract damages. See Jackson v. Paterno, 128 A.D. 474, 478 (N.Y. App. Div. 1908) (denying claim because "there was no damage proved"); Bouzianis v. U. S. Air, *Inc.*, 1985 U.S. Dist. LEXIS 15470, 13-15 (D. Mass. Sept. 30, 1985) (same).

remedy must be measured by what it actually paid Abbott to date for the purported promise not to

increase Norvir's price in the U.S. market. Again, this amount is zero.

#### III. Abbott Is Entitled To Summary Judgment On GSK's Claim Under North Carolina's **Unfair And Deceptive Trade Practices Act.**

In Count 3 of its amended complaint, GSK alleges that Abbott's conduct violates the UDTPA, N.C. Gen. Stat. § 75-1.1. Summary judgment on this claim is appropriate because "[t]he question of what constitutes an unfair or deceptive trade practice is an issue of law." Nelson v. Hartford Underwriters Ins. Co., 177 N.C. App. 595, 609 (N.C. App. 2006) (granting summary judgment for defendant). To state a claim under the UDTPA, a plaintiff must allege: "(1) an unfair or deceptive act or practice, or unfair method of competition, (2) in or affecting commerce, and (3) which proximately caused actual injury to the plaintiff or his business." Miller v. Nationwide Mut. Ins. Co., 435 S.E.2d 537, 542 (N.C. Ct. App. 1993); see also 4/11/08 Order at 22.

In its previous order denying Abbott's motion to dismiss, this Court found that "GSK has alleged conduct that could be considered 'unfair' or 'deceptive' under the Act." (4/11/08 Order at 24). But the undisputed evidence does not support these allegations.

#### **GSK Cannot Prove "Unfair" Conduct Based On Its Flawed Antitrust And** Α. **Contract Theories.**

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GSK attempts to repackage its antitrust and breach of contract allegations as "unfair" conduct that violates the UDTPA. This attempt must fail. First, the implied promise allegations cannot form the basis of an "unfair" conduct claim. North Carolina courts have made it clear that contractual conduct that falls short of a breach is not "unfair" under the statute. McLamb v. T.P. Inc., 619 S.E.2d 577, 592 (N.C. Ct. App. 2005) (affirming dismissal of UDTPA claim "because plaintiffs did not have any contract rights under the reservations [and thus] they could not allege any damage by virtue of defendant's alleged unfair and deceptive acts"). As shown above, Abbott has not breached the implied covenant of good faith and fair dealing. GSK cannot disguise its failed contract claim as "unfair" conduct under the UDTPA.

Even if GSK could prove a breach of the implied covenant of good faith and fair dealing, "a mere breach of contract, even if intentional, is not sufficiently unfair or deceptive to sustain an action under" the UDTPA. Branch Banking & Trust Co. v. Thompson, 418 S.E.2d 694, 700 (N.C. Ct. App. 1992). Instead, "a plaintiff must show substantial aggravating circumstances attending the breach to recover under the Act." Bartolomeo v. S.B. Thomas, Inc., 889 F.2d 530, 535 (4th Cir. 1989). As the Fourth Circuit has recognized in interpreting the UDTPA, "unfairness inheres in every breach of contract when one of the parties is denied the advantage for which he contracted." *United Roasters*, Inc. v. Colgate-Palmolive, Co., 649 F.2d 985, 992 (4th Cir. 1981). As a result, "a broken promise is unfair or deceptive only if the promisor had no intent to perform when he made the promise." Gilbane Bldg. Co. v. Federal Reserve Bank of Richmond, Charlotte Branch, 80 F.3d 895, 903 (4th Cir. 1996) (quotations and citations omitted). Thus, "the words [of the UDTPA] must mean something more than an ordinary contract breach," even if intentional. Id. Regardless of their merit, therefore, GSK's contract allegations cannot support the UDTPA claim.

Second, as discussed above, GSK's allegations do not state a viable claim for relief under the antitrust laws. This Court previously held in the motion to dismiss context that it would apply the same antitrust standard to the UDTPA that it applies to GSK's Sherman Act claim. (4/11/08 Order at 23). Thus, dismissal of GSK's Sherman Act claim also would dispose of GSK's UDTPA claim to the extent it is based on the same allegations.

North Carolina courts have reached this same conclusion under similar circumstances. See,

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e.g, R. J. Reynolds Tobacco Co. v. Philip Morris, 199 F. Supp. 2d 362, 396 (M.D.N.C. 2002) (granting summary judgment on a deceptive trade practices claim because it merely alleged same facts as failed antitrust claim); Sea-Roy Corp. v. Parts R Parts, 1997 U.S. Dist. LEXIS 21809, 64 n.25 (M.D.N.C. Dec. 2, 1997) (dismissing UDPTA trade practices claim based on failed federal antitrust claims). This makes sense. If the law were otherwise, the UDTPA would chill conduct that is, or at least potentially is, *pro*competitive – such as comparatively low, but not below-cost, pricing. Thus, the UDTPA claim cannot survive based on GSK's failed antitrust allegations.

#### B. **GSK Cannot Prove That Abbott's Conduct Was "Deceptive."**

The evidence also does not support GSK's allegations of deception. A trade practice is deceptive if it "has the capacity or tendency to deceive." Carolina Water Service, Inc. of North Carolina v. Town of Atlantic Beach, 464 S.E.2d 317, 321 (N.C. Ct. App. 1995) (finding no UDTPA violation on summary judgment). To demonstrate this, plaintiffs must present evidence of "the effect of defendant's conduct on the consuming public." Rucker v. Huffman, 99 N.C. App. 137, 141-42 (N.C. Ct. App. 1990). North Carolina law also requires that "the plaintiff establish[] causation between the deceptive acts and a compensable injury." (Order at 24 n.14 (citing Business Cabling, *Inc. v. Yokeley*, 643 S.E.2d 63 (N.C. Ct. App. 2007)).

GSK has offered no fact or expert testimony on deceptive conduct and cannot otherwise prove deceptive statements or proximately caused injury. According to GSK's Amended Complaint, Abbott (1) "deliberately deceived its competitors and the public as to the true and illegitimate nature of the price increase"; and (2) "further misrepresented the pricing of Norvir to the public." (Am. Compl. ¶ 76). In support, GSK cites a chart published by Abbott entitled "Daily Cost of Common ARV Agents," which compared Norvir's boosting price with the price of other HIV drugs at their most common dose. (Am. Compl. ¶¶ 37-38). FDA criticized this chart because it cited the "unapproved" 100 mg booster dose of Norvir rather than the 1200 mg dose "approved" for Abbott's Norvir label. (See Ex. T, Devlin Dep. at 13:14-23 & Ex. 1).

GSK's "deception" claim fails for three independent reasons. First, GSK cannot prove that any statements were "deceptive" under the UDTPA. No witness deposed in this case testified that he or she was deceived by the chart. And GSK has offered no expert testimony on the topic. This is

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not surprising. Abbott's pricing chart accurately reflects the correct wholesale price of the most common daily dose for Norvir at the time (100 mg). (Id.) As the chart makes clear in footnote 1, FDA approved this dose in the Reyataz label. (*Id.*)

Second, GSK also has failed to show any injury proximately caused by any alleged "deceptive" statements. North Carolina courts have consistently found that plaintiffs must show that they "suffered actual injury as a proximate result of defendant's deceptive statement or misrepresentation." Sharpe v. American Family Publishers, 25 F.3d 1040 (4th Cir. 1994) (affirming summary judgment on this ground under North Carolina law); accord Bailey v. LeBeau, 79 N.C. App. 345, 352 (N.C. Ct. App. 1986) (dismissing UDTPA claim because plaintiff failed to show any proximate injury from deception).

Given that GSK has no proof of deception in the first place, it certainly has no evidence of proximately caused injury. Again, no fact or expert witness testified on this issue. See Anders v. Hyundai Motor Am. Corp., 407 S.E.2d 618, 622-23 (N.C. Ct. App. 1991) (affirming summary judgment because "plaintiff cannot show any injury resulting from the alleged deceptive statement"); Sunset Beach Development, LLC v. AMEC, Inc., 675 S.E.2d 46, 53 (N.C. App. 2009) (same).

Third, GSK cannot satisfy the reliance element. This Court previously noted that one North Carolina court stated that "actual reliance on a misrepresentation is not required." (4/11/08 Order at 24 (citing Cullen v. Valley Forge Life Ins. Co., 589 S.E.2d 423, 431 (N.C. App. 2003)). But the North Carolina Court of Appeals recently held that "actual reliance" is required under the UDTPA. Hospira Inc. v. Alphagary Corp., 671 S.E.2d 7, 12 (N.C. App. 2009) (affirming summary judgment on this ground and distinguishing Cullen as decided under the Insurance Act, N.C. Gen. Stat. § 58-63-15(1)). Although the Court need not reach the issue, summary judgment also is proper because GSK has no evidence that anyone relied on Abbott's drug chart to their detriment.

#### **CONCLUSION**

For the foregoing reasons, this Court should grant Abbott's motion for summary judgment.

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